DEPUTY SECRETARY OF DEFENSE
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WASHINGTON, DC 20301-1010

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The Honorable J. Dennis Hastert
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

I am pleased to forward the enclosed final report in response to Section 701 of the National Defense Authorization Act for Fiscal Year 2000 requiring four semiannual reports regarding the Pharmacy Benefits Program.

The report details the actions taken to establish an effective, efficient, integrated pharmacy benefits program including steps toward establishing a Uniform Formulary, a Department of Defense Pharmacy and Therapeutics Committee, a Uniform Formulary Beneficiary Advisory Panel, and the status of implementation of the Pharmacy Data Transaction Service.

Thank you for your continued interest in the Military Health System.

Sincerely,

Paul Wolfowitz

Enclosure:
As stated

Report to Congress

Report on Pharmacy Benefits Program

PHARMACY BENEFITS PROGRAM

This is the fourth and final semi-annual report to Congress required by Section 701 (c) of the National Defense Authorization Act for Fiscal Year 2000 regarding the Department's Pharmacy Benefits Program. The Act requires the Department to report on our implementation of the uniform formulary (UF) required under title 10, United States Code, section 1074g, the results of a confidential survey of prescribers, and the operation of the Pharmacy Data Transaction Service (PDTS) required by subsection (e) of 1074g.

Implementation of a UF under the Act requires:

- Establishment of procedures to create a UF based upon relative clinical effectiveness and cost effectiveness.
- Establishment of procedures to assure the availability of clinically appropriate non-formulary pharmaceutical agents to members of the uniformed forces.
- Establishment of an expeditious peer review system for other beneficiaries to receive pharmaceutical agents not on the UF but considered clinically necessary.
- Establishment of procedures for prior authorization when required.
- Establishment of a Department of Defense Pharmacy and Therapeutics Committee (DoD P&T) not later than 30 days after the enactment of the Act (which was October 5, 1999).
- Establishment of a Uniform Formulary Beneficiary Advisory Panel

The Act also allows the establishment of cost sharing requirements for generic, formulary and non-formulary agents.

The Department was unable to establish the DoD P&T Committee required by the Act within 30 days of enactment of the Act. The Act requires the DoD P&T Committee to include not only government employees, but non-government personnel as well. We are required to comply with the Federal Advisory Committee Act (FACA), and because of the lengthy nomination and approval process, we have been unable to comply yet with this requirement.

The process to establish a DoD P&T Committee and Advisory Panel under FACA guidelines has been underway since October 1999. We have completed the Charters for the DoD P&T Committee and Advisory Panel. Beneficiary organizations submitted nominations of individuals to serve on the Advisory Panel to represent the DoD beneficiaries. Selection of members and alternates for the Advisory Panel has been approved by the White House Liaison office. We have notified selectees and have obtained required financial disclosure documents. Nominations for membership on the DoD P&T Committee were approved by the White House Liaison Office in June 2001. Members and alternates have been notified. We anticipate the first meeting of these committees to take place in the Spring of 2002 following publication of the Final Rule implementing UF procedures.

The Department is developing policies and procedures for a UF that will:

- comply with statutory requirements

- make medications more uniformly available to beneficiaries
- facilitate the delivery of effective and efficient drug therapy within the resources available to the Department
- preserve the integrity of existing DoD and DoD/VA national pharmaceutical contracts and allow national contracts to be established in the future
- be easy to understand

The Act requires the Department to implement the UF not later than October 1, 2000. The Department did not meet this deadline. The proposed regulation has been written and is in coordination within the Department.

The DoD P&T Committee, whose role is to develop and maintain the UF, will consist of government and non-government clinical staff as required by the Act. In accordance with the Act, the DoD P&T Committee will presume inclusion of a pharmaceutical agent on the UF unless the pharmaceutical agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other drugs included on the UF. The UF will be developed through a six-step process. First, the DoD P&T Committee will identify the therapeutic classes. Second, it will identify the eligible pharmaceutical agents within each class. Third, the DoD P&T Committee will evaluate the agents within each class to determine their relative safety, effectiveness and clinical outcomes. Fourth, the DoD P&T Committee will consider the costs of the agents within each class in relation to the safety, effectiveness and clinical outcomes to determine their relative cost-effectiveness. Fifth, the Committee will use the information identified in steps 3 and 4 to identify agents that should not be included on the UF. Sixth, the DoD P&T Committee will forward their recommendations to the Uniform Formulary Beneficiary Advisory Panel for review and comment.

The UF will include a sufficient array of generic and brand name drugs in a complete range of therapeutic classes to support the nationwide scope of pharmaceutical care that is provided by the DoD National Mail Order Pharmacy (NMOP) and the retail pharmacy networks. The Act does not require Military Treatment Facilities (MTFs) to have available to beneficiaries the entire UF, but only pharmaceutical agents consistent with the scope of health care services offered in the facility. Every MTF that offers enrollment with primary care managers provides as a minimum a primary care scope of healthcare services. Each of these MTFs will be required to have available a subset of the agents on the UF known as the Basic Core Formulary (BCF). The BCF is the minimum set of pharmaceutical agents that must be included on the MTF formulary. Other agents may be added to the MTF formulary based on the specific scope of health care services offered in the MTF.

Pharmaceutical agents not included on the UF will be classified as non-formulary. Agents designated as non-formulary will be available through the retail pharmacies and NMOP at copays higher than those established for agents included on the UF. Non-formulary agents will not be available in the MTFs unless determined to be clinically appropriate for active duty members or clinically necessary for all others, whereupon the MTF will obtain the agent. Non-formulary agents are recommended by the DoD P&T Committee and may include brand name products for which a generic equivalent is available on the UF, and drugs not as clinically effective and/or cost-effective as formulary agents. Agents that are not approved by the U.S.

Food and Drug Administration for commercial marketing or that are exclusively for treatment of a non-covered benefit are excluded from consideration on the UF.

A limited number of pharmaceutical agents, identified by the DoD P&T Committee, will require prior authorization before dispensing. Prior authorization will be used judiciously as a means to assure the prescribing of specific medications for clinical appropriateness.

For purposes of cost sharing, the UF will be divided into a three-tiered co-payment structure: Generic, Formulary, and Non-formulary. A new copay structure was implemented April 1, 2001 and is no longer based on beneficiary status, except for active duty members who never pay copays. The revised co-pay amounts simplify the cost share structure and are consistent with the best business practices used in the private sector. Until full implementation of the UF, cost sharing is based on pharmaceutical agent's status as generic or formulary and its point of sale (i.e., network or non-network retail pharmacy, or NMOP) from which the medication was acquired. The cost share for generic agents is $3 and the cost sharing for formulary brandname products is $9. Cost sharing amounts were selected to assure that all beneficiaries could obtain a reduction in their current cost sharing through use of generic products, and that brand-name cost sharing was substantially higher than generics without unduly penalizing beneficiaries in relation to their current cost share levels.

The statute also requires a confidential survey of prescribers at MTFs and TRICARE contractors to evaluate and analyze the impact of the UF. A baseline survey will be initiated prior to implementation of the UF. RAND's National Defense Research Institute designed the baseline survey and fielded it in July 2001.

Worldwide implementation of PDTS in all MTFs, TRICARE Managed Care Support Contract retail networks, and the NMOP was completed on June 25, 2001.

In summary, the Department is proceeding with implementing a UF and an Integrated Pharmacy System. The implementation timeline for the UF is contingent on the start-up of the Beneficiary Advisory Panel and the DoD Formulary P&T Committee, and publication of a Final Rule implementing the UF under the Pharmacy Benefits Program.